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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FORD, VANESSA L	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/545,772	WILKINS ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,6,13-15,19,20,23-26,28-31,36-39,62 and 64-66* is/are pending in the application.

4a) Of the above claim(s) *64-66* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,6,13-15,19,20,23-26,28-31,36-39 and 62* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

FINAL ACTION

1. This Office Action is responsive to Applicant's amendment and response filed December 11, 2003. Claim has been amended. Claims 2, 4-5, 7-12, 16-18, 21-22, 27, 32, 34-35, 40-61 and 63 have been cancelled. Claims 64-66 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Rejections Withdrawn

3. In view of Applicant's amendment and response the following rejections have been withdrawn:

a) rejection of claims 1,3,6, 13-15, 19-20, 23-26, 28-31, 33, 36-39 and 62-63 under 35 U.S.C. 112, first paragraph, pages 2-6, paragraph 2 of the previous Office action.

b) rejection of claims 1,3, 6, 13-15, 19-20, 23-26, 28-31, 33, 36-39 and 62-63 under 35 U.S.C. 112, second, paragraph, pages 6-7, paragraph 3 of the previous Office action.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 3, 6, 13-15, 19-20 and 23-24 and 36-39 are rejected under 35 U.S.C. 103(a) as unpatentable Thomas, Jr. et al *(U.S. Patent No. 5,919,463, filed October 16, 1995)* in view of Schneerson et al *(Infection and Immunity, September, 1992, p. 3528-3532).*

Claims 1, 3, 6, 13-15, 19-20 and 23-24 and 36-39 are drawn to an immunogenic composition for eliciting an immune response to a pathogenic organism which composition comprises a recombinant protein conjugated to polysaccharide component, wherein said protein comprises the toxin A repeating units (rARU) of *Clostridium difficile* and said polysaccharide component is an antigen of a pathogenic microorganism, which pathogenic microorganism is other than *C. difficile* wherein said composition is formulated for injection, wherein the pathogenic organism is *Streptococcus pneumoniae.*

Thomas, Jr. et al disclose a composition that contains an antigen, a toxin (*Clostridum difficile, C. novyi, C. sordellii, C. perfringens, C. tetani and C. botulinum*) or a fragment or derivative thereof having adjuvant activity in a pharmaceutically acceptable vehicle (i.e. water, a saline solution, phosphate-buffered saline, a bicarbonate solution or a form of a suppository) (column 1). Thomas, Jr. et al disclose that the *C. difficile* toxins contain the ARU which is the carboxyl-terminal fragment of *C. difficile* toxins A or B having adjuvant activity (column 1). Thomas, Jr. disclose that the toxins of the invention may be covalently coupled or chemically cross-linked to an antigen by standard methods (column 2). Thomas, Jr. et al disclose that intranasal

administration of antigens give rise to mucosal immune responses in the upper respiratory tract, gastrointestinal and genito-urinary tracts (column 4). Thomas, Jr. et al disclose that the compositions of the invention can be administered to a patient using standard methods which include oral, rectal, vaginal, intravenous, subcutaneous, intraperitoneal or intramuscular administration (column 3).

Thomas, Jr. et al do not teach serotype 14 *Streptococcus pneumoniae*.

Schneerson et al teach that the 14 *Streptococcus pneumoniae* capsular polysaccharide is poorly immunogenic among the pneumococcal capsular polysaccharides (page 3528). Schneerson et al teach that the development of polysaccharide protein conjugates for prevention of systemic infection caused by *Haemophilus inflenzae* type b serves as a precedent for making conjugates of polysaccharides of other capsulated pathogens (page 3528). Schneerson teach that conjugation of antigen to improve the immunological properties of other polysaccharides such as *Streptoococcus pneumoniae* have been used (page 3528). Schneerson et al teach a conjugate vaccine composed of serotype 14 *Streptococcus pneumoniae* capsular polysaccharide (PN14) bound to Pertussis Toxin. Schneerson et al teach that Pertussis toxin is both a virulence factor and protective antigen of *Bordetella pertussis*. Schneerson et al devised a synthetic scheme to prepare a conjugate of serotype 14 *Streptococcus pneumoniae* and Pertussis toxin. Schneerson et al further teach that the serotype 14 *Streptococcus pneumoniae*-Pertussis toxin conjugate elicited antibodies in mice to serotype 14 *Streptococcus pneumoniae* at levels estimated to be protective in humans and elicited neutralizing antibodies to Pertussis toxin (see the Abstract).

It would be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add the serotype 14 *Streptococcus pneumoniae* capsular polysaccharides of Schneerson et al to the immunogenic composition as taught by Thomas, Jr. et al because Schneerson et al demonstrates that 14 *Streptococcus pneumoniae* capsular polysaccharides are poorly immunogenic, but conjugating these capsular polysaccharides to proteins enhances their immunogenicity (3528). It would be expected barring evidence to the contrary that an immunogenic composition comprising the serotype 14 *Streptococcus pneumoniae* capsular polysaccharides of Schneerson et al and the *C. difficile* toxins contain the ARU which is the carboxyl-terminal fragment of *C. difficile* toxins A or B having adjuvant activity of Thomas, Jr. et al would be effective in protecting against a pathogenic microorganism because Schneerson et al teach that covalent attachment of PN14 to protein conferred enhanced immunogencity and T cell dependence (page 3530). Additionally, Thomas, Jr. et al teach that ARU when added to antigen leads to effective mucosal immune responses (column 1).

5. Claims 1, 3, 6, 13-15, 19-20, 25-26 and 36-39 as unpatentable over Thomas, Jr. et al *(U.S. Patent No. 5,919,463, filed October 16, 1995)* in view of Taylor et al *(Infection and Immunity, September 1993, p. 3678-3687).*

Claims 1, 3, 6, 13-15, 19-20, 25-26 and 36-39 are drawn to an immunogenic composition for eliciting an immune response to a pathogenic organism which composition comprises a recombinant protein conjugated to polysaccharide component,

wherein said protein comprises the toxin A repeating units (rARU) of *Clostridium difficile* and said polysaccharide component is an antigen of a pathogenic microorganism, which pathogenic microorganism is other than *C. difficile* wherein said composition is formulated for injection, wherein the pathogenic organism is *Shigella flexneri.*

Thomas, Jr. et al disclose a composition that contains an antigen, a toxin (*Clostridium difficile, C. novyi, C. sordellii, C. perfringens, C. tetani and C. botulinum*) or a fragment or derivative thereof having adjuvant activity in a pharmaceutically acceptable vehicle (i.e. water, a saline solution, phosphate-buffered saline, a bicarbonate solution or a form of a suppository) (column 1). Thomas, Jr. et al disclose that the *C. difficile* toxins contain the ARU which is the carboxyl-terminal fragment of *C. difficile* toxins A or B having adjuvant activity (column 1). Thomas, Jr. disclose that the toxins of the invention may be covalently coupled or chemically cross-linked to an antigen by standard methods (column 2). Thomas, Jr. et al disclose that intranasal administration of antigens give rise to mucosal immune responses in the upper respiratory tract, gastrointestinal and genito-urinary tracts (column 4). Thomas, Jr. et al disclose that the compositions of the invention can be administered to a patient using standard methods which include oral, rectal, vaginal, intravenous, subcutaneous, intraperitoneal or intramuscular administration (column 3).

Thomas, Jr. et al do not teach *Shigella flexneri* Type 2a.

Taylor et al teach a conjugate vaccine comprising *Shigella dysenteria* type 1, *Shigella flexneri* type 2a and *Shigella sonnei* bound to bacterial toxoids (carrier proteins). Taylor et al teach that *Shigella dysenteria* type 1, *Shigella flexneri* type 2a

and *Shigella sonnei* administered to mice alone are not immunogenic. Taylor et al further teach that *Shigella dysenteria* type 1, *Shigella flexneri* type 2a and *Shigella sonnei* conjugated to a carrier protein injected into mice subcutaneously in saline solutions elicited serum IgG and IgM antibodies with booster responses. When the *Shigella dysenteria* type 1, *Shigella flexneri* type 2a and *Shigella sonnei* conjugate were adsorbed with alum further enhancement of their immunogenicity was observed (see the Abstract).

It would be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add the *Shigella flexneri* 2a capsular polysaccharides of Taylor et al to the immunogenic composition as taught by Thomas, Jr. et al because Taylor et al teach that *Shigella flexneri* 2a capsular polysaccharides are poor immunogens when administered alone, but conjugating these capsular polysaccharides to proteins enhances their immunogenicity (the entire article). It would be expected barring evidence to the contrary that an immunogenic composition comprising the *Shigella flexneri* 2a capsular polysaccharides of Taylor et al and the *C. difficile* toxins contain the ARU which is the carboxyl-terminal fragment of *C. difficile* toxins A or B having adjuvant activity of Thomas, Jr. et al would be effective in protecting against a pathogenic microorganism because Taylor et has demonstrated that conjugated injected into mice elicited serum IgG and IgM antibodies with booster responses and adsorption onto alum enhanced immunogenicity (see the Abstract). Taylor et al teach that *Shigella flexneri* 2 a conjugates conferred protective levels of IgG antibodies (page 3684).

Additionally, Thomas, Jr. et al teach that ARU when added to antigen leads to effective mucosal immune responses (column 1).

6. Claims 1, 3, 6, 13-15, 19-20, 28-29, 36-39 and 62 are rejected under 35 U.S.C. 103(a) as unpatentable over Thomas, Jr. et al *(U.S. Patent No. 5,919,463, filed October 16, 1995)* in view of Devi et al *(Proc. National Academy of Science, Volume 88, August 1991, p. 7175-7179).*

Claims 1, 3, 6, 13-15, 19-20, 28-29, 36-39 and 62 are drawn to an immunogenic composition for eliciting an immune response to a pathogenic organism which composition comprises a recombinant protein conjugated to polysaccharide component, wherein said protein comprises the toxin A repeating units (rARU) of *Clostridium difficile* and said polysaccharide component is an antigen of a pathogenic microorganism, which pathogenic microorganism is other than *C. difficile* wherein said composition is formulated for injection, wherein the pathogenic organisms are *Escherichia coli* and *Neisseria meningitidis.*

Thomas, Jr. et al disclose a composition that contains an antigen, a toxin (*Clostridium difficile, C. novyi, C. sordellii, C. perfringens, C. tetani and C. botulinum*) or a fragment or derivative thereof having adjuvant activity in a pharmaceutically acceptable vehicle (i.e. water, a saline solution, phosphate-buffered saline, a bicarbonate solution or a form of a suppository) (column 1). Thomas, Jr. et al disclose that the *C. difficile* toxins contain the ARU which is the carboxyl-terminal fragment of *C.*

difficile toxins A or B having adjuvant activity (column 1). Thomas, Jr. disclose that the toxins of the invention may be covalently coupled or chemically cross-linked to an antigen by standard methods (column 2). Thomas, Jr. et al disclose that intranasal administration of antigens give rise to mucosal immune responses in the upper respiratory tract, gastrointestinal and genito-urinary tracts (column 4). Thomas, Jr. et al disclose that the compositions of the invention can be administered to a patient using standard methods which include oral, rectal, vaginal, intravenous, subcutaneous, intraperitoneal or intramuscular administration (column 3).

Thomas, Jr. et al do not teach *Escherichia coli* K1 or *Neisseria meningitidis* serogroup B.

Devi et al teach that the capsular polysaccharides of *Escherichia coli* K1 and *Neisseria meningitidis* serogroup B are identical (poly{(2→8)-α-N-acetylneuaminic acid)} or poly(α2-8NeuNAc) and serve as essential virulence factors and protective antigens for both pathogens. Devi et al teach that capsular polysaccharides are poor immunogens when administered alone, but conjugating these capsular polysaccharides to tetanus toxin (carrier proteins) enhances their immunogenicity (the Abstract). Devi et al teach that attempts have been made to induce protective immunity to *Escherichia coli* K1 and *Neisseria meningitidis* serogroup B have been thwarted because poly(α2-8NeuNAc), alone or complexed to outer membrane proteins induced low transient levels of IgM antibodies (page 7175). Devi et al teach that when the capsular polysaccharides of *Escherichia coli* K1 and *Neisseria meningitidis* serogroup B are conjugated to tetanus toxin (a carrier protein) and injected into mice in a saline

solution the capsular polysaccharides elicit both poly(α2-8NeuNAc) IgM and IgG antibodies. Devi et al further teach that re-injection elicited booster responses of both isotypes (T-dependent properties) at dosages applicable for clinical use (page 7178).

It would be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add the capsular polysaccharides of *Escherichia coli* K1 and *Neisseria meningitidis* serogroup B as taught by Devi et al to the immunogenic composition as taught by Thomas, Jr. et al because Devi et al teach that capsular polysaccharides are poor immunogens when administered alone, but conjugating these capsular polysaccharides to tetanus toxin (carrier proteins) enhances their immunogenicity (the entire article). It would be expected barring evidence to the contrary that an immunogenic composition comprising the capsular polysaccharides of *Escherichia coli* K1 and *Neisseria meningitidis* serogroup B as taught by Devi et al and the *C. difficile* toxins contain the ARU which is the carboxyl-terminal fragment of *C. difficile* toxins A or B having adjuvant activity of Thomas, Jr. et al would be effective in protecting against a pathogenic microorganism because Devi et al demonstrated that *Escherichia coli* K1 and *Neisseria meningitidis* serogroup B antigens when conjugated to tetanus toxoid elicited 90.% and 100% IgG antibodies, respectively (see Table 4, page 7178). Additionally, Thomas, Jr. et al teach that ARU when added to antigen leads to effective mucosal immune responses (column 1).

7. Claims 1, 3, 6, 13-15, 19, 30-31, 33 and 36-39 are rejected under 35 U.S.C. 103(a) as unpatentable over Thomas, Jr. et al *(U.S. Patent No. 5,919,463, filed October 16, 1995)* in view of Fattom et al *(Infection and Immunity, July 1990, 2367-2374).*

Claims 1, 3, 6, 13-15, 19, 30-31, 33 and 36-39 are drawn to an immunogenic composition for eliciting an immune response to a pathogenic organism which composition comprises a recombinant protein conjugated to polysaccharide component, wherein said protein comprises the toxin A repeating units (rARU) of *Clostridium difficile* and said polysaccharide component is an antigen of a pathogenic microorganism, which pathogenic microorganism is other than *C. difficile* wherein said composition is formulated for injection, wherein the pathogenic organism is *Staphylococcus aureus.*

Thomas, Jr. et al disclose a composition that contains an antigen, a toxin (*Clostridum difficile, C. novyi, C. sordellii, C. perfringens, C. tetani and C. botulinum*) or a fragment or derivative thereof having adjuvant activity in a pharmaceutically acceptable vehicle (i.e. water, a saline solution, phosphate-buffered saline, a bicarbonate solution or a form of a suppository) (column 1). Thomas, Jr. et al disclose that the *C. difficile* toxins contain the ARU which is the carboxyl-terminal fragment of *C. difficile* toxins A or B having adjuvant activity (column 1). Thomas, Jr. disclose that the toxins of the invention may be covalently coupled or chemically cross-linked to an antigen by standard methods (column 2). Thomas, Jr. et al disclose that intranasal administration of antigens give rise to mucosal immune responses in the upper respiratory tract, gastrointestinal and genito-urinary tracts (column 4). Thomas, Jr. et al

disclose that the compositions of the invention can be administered to a patient using standard methods which include oral, rectal, vaginal, intravenous, subcutaneous, intraperitoneal or intramuscular administration (column 3).

Thomas, Jr. et al do not teach *Staphylococcus aureus* Type 5 or Type 8 capsular polysaccharides.

Fattom et al teach vaccines composed of *Staphylococcus aureus* type 5 and Type 8 capsular polysaccharides conjugated to *Pseudomonas aerginosa* Exotoxin A. Fattom et al teach that *Staphylococcus aureus* type 5 and type 8 capsular polysaccharides are virulence factors and protective antigens for bacteremia caused by *Staphylococcus aureus* (page 2368). Fattom et al teach that *Staphylococcus aureus* type 5 and type 8 capsular polysaccharides are poor immunogens in humans when administered alone, but conjugating these capsular polysaccharides to proteins enhances their immunogenicity both for active immunization and for preparing high-titered antisera in volunteers for passive immunization (page 2368). Fattom et al teach that when *Staphylococcus aureus* type 5 and type 8 capsular polysaccharides are bound to a protein (i.e. *Pseudomonas aerginosa* exotoxin A) to form a conjugate both *Staphylococcus aureus* type 5 and type 8 elicit antibody responses. Fattom et al teach that *Staphylococcus aureus* type 5 and type 8 capsular polysaccharides acquire T-cell dependent properties as shown by their ability to respond to carrier priming and thus stimulate booster responses (see the Abstract).

It would be *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add the *Staphylococcus aureus* type 5 and type 8 capsular

polysaccharides of Fattom et al to the immunogenic composition as taught by Thomas, Jr. et al because Fattom et al teach that the *Staphylococcus aureus* type 5 and type 8 capsular polysaccharides are poor immunogens in humans when administered alone, but conjugating these capsular polysaccharides to proteins enhances their immunogenicity both for active immunization and for preparing high-titered antisera in volunteers for passive immunization (page 2368). It would be expected barring evidence to the contrary that an immunogenic composition comprising the *Staphylococcus aureus* type 5 and type 8 capsular polysaccharides and the *C. difficile* toxins contain the ARU which is the carboxyl-terminal fragment of *C. difficile* toxins A or B having adjuvant activity of Thomas, Jr. et al would be effective in protecting against a pathogenic microorganism because Fattom et al teach that the *Staphylococcus aureus* type 5 and type 8 capsular polysaccharide conjugated elicited as rise in CP antibodies and both S. aureus CPs acquired T cell dependent properties as shown by their ability to respond to carrier priming and to stimulate booster responses (see the Abstract). Fattom et al teach that clinical studies the two conjugates were effective in both active and passive immunization (see the Abstract). Additionally, Thomas, Jr. et al teach that ARU when added to antigen leads to effective mucosal immune responses (column 1).

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

9. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Vanessa L. Ford
Biotechnology Patent Examiner
April 26, 2004

NITA MINNIFIELD
PRIMARY EXAMINER
5/3/04